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The Honorable Jennifer C. Boal
United States Magistrate Judge
District of Massachusetts
John Joseph Moakley Federal Courthouse
1 Courthouse Way, 5th Floor
Boston, MA 02210

Re: *In re New England Compounding Pharmacy, Inc. Products Liability Litigation*,
Master Dkt.: 1:13-md-02419-FDS; MDL No. 2419

Dear Judge Boal:

I write on behalf of the Plaintiffs' Steering Committee to ask whether Your Honor would be willing to hear potential appeals from the Settlement Administrator's determinations on victims' claims made in the bankruptcy settlement.

The Chapter 11 Trustee for NECC will soon publicly propose a plan of reorganization ("the Plan"). The Plan includes an objective settlement matrix, created with input from physicians who have treated hundreds of victims, that controls the amounts each victim will receive according to specific criteria. Since the rules governing this process are clear, the PSC does not expect a large number of appeals from the Settlement Administrator's awards nor that resolving any appeal will be time consuming.

In our view, Your Honor is best-suited for this role. Your Honor's experience with the case, judicial experience, and temperament cannot be duplicated by a private mediator. The PSC is also concerned about the impact that retaining a private mediator will have on the victims' total recovery.

We recognize that Your Honor may wish to consider this request without a public inquiry. I therefore write privately to gauge Your Honor's interest, copying only Judge Zobel. As none of the settling defendants has an interest in the claim, I do not believe this communication need be docketed nor disclosed.

Let me stake out what our request may entail. As Your Honor is familiar with the litigation proceeding against NECC and other defendants in the MDL, and is aware that a settlement has been reached with NECC, its insiders, its insurers, and some related entities, I focus below on the procedural aspects of how the soon-to-be proposed bankruptcy plan accomplishes the task of getting money to victims. I also lay out the proposed roles of the Settlement Administrator and, if you agree to serve in this capacity, the Magistrate Judge. These

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descriptions are based on the current draft of the “Claims Resolution Procedures,” which will be a publicly available attachment to the Plan.

Overview of the Settlements.

The settlements with NECC, its affiliates, owners, and some of their insurance companies provide for about \$70M in cash and possibly an additional \$30-38M in the future to the Bankruptcy Estate (“NECC Settlements”). The Bankruptcy Court has approved the NECC Settlements.¹

We expect other multiple national defendants, defendants who are liable to all victims if they are liable to any victims, to contribute additional funds to the Bankruptcy Estate (collectively with the NECC Settlements, the “National Settlements”). We also expect a number of clinic, hospital and doctor defendants that purchased and/or injected the contaminated MPA to contribute additional funds to the Bankruptcy Estate (the “Clinic Settlements”).

So how does the money get from Bankruptcy Estate to the victims?

Plan of Reorganization and Funding the Tort Trust.

The Chapter 11 Trustee, with the support of the Plaintiffs’ Steering Committee and the Creditors’ Committee, will file the Plan in the next few weeks. The Plan provides that the Chapter 11 Trustee will fund a Tort Trust that distributes compensation to victims of the outbreak. The sole purpose of the Tort Trust is to serve as a mechanism for liquidating, converting to cash, and distributing the Tort Trust assets for the benefit of the tort claimants.

A substantial portion of the funds from the National Settlements will be transferred from the Bankruptcy Estate to the Tort Trust for distribution to all victims. Funds contributed through Clinic Settlements will also be deposited in the Tort Trust, but those funds will be segregated and will be distributed, after expenses, only to patients who received contaminated MPA injections at each particular settling clinic.

The Tort Trustee Establishes and Oversees the Tort Trust.

The Tort Trustee will be responsible for establishing and overseeing the Tort Trust. The Tort Trustee will pay all expenses of the Trust, file tax returns, issue 1099s and make all payments to Claimants after Claims have been finally resolved.

The Settlement Matrix Governs Claim Awards.

As is common in mass tort-related bankruptcies, the Plan includes a proposed settlement matrix (“Matrix”) for determining the value of tort victims’ claims. The Matrix was designed to

¹ Orders approving 9019 settlement motions, Dkts. 970-974, *In re New England Compounding Pharmacy, Inc.*, 12-19882 (HJB) (Chapter 11).

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distinguish among the most serious cases and the less serious cases. The Matrix was created with help from doctors who treated hundreds of patients injured by NECC's contaminated MPA and after a careful review of the published medical literature concerning the outbreak. Due to the limited funds that will be available to claimants from the National Settlements, a primary goal was balancing the need to compensate distinctly situated claimants differently, while also minimizing the administrative expenses of reviewing and approving claims.

Claimants who establish that they received an injection or injections from one or more of the Three Contaminated MPA Lots may apply to the Settlement Administrator for one of the following seven disease or medical condition categories (the "Base Point Categories"):

| Category | Description | Base Points |
|--------------|---|-------------|
| Category I | Death after MPA Injection <i>and</i> (1) Spinal or Paraspinal Fungal Infection ² and/Or (2) Fungal Meningitis | 55 |
| Category II | Non-Death Fungal Meningitis <i>and</i> Spinal or Paraspinal Fungal Infection after MPA Injection | 40 |
| Category III | Non-Death Fungal Meningitis after MPA Injection | 30 |
| Category IV | Non-Death Spinal <i>or</i> Paraspinal Fungal Injection after MPA Injection | 20 |
| Category V | Peripheral Joint Fungal Infection ³ after MPA Injection | 10 |
| Category VI | Symptoms of Headache, Word-Finding Difficulty, Nausea/Vomiting, Fever, Neck Stiffness or Pain, Back Pain, Photophobia, Lack of Appetite, Urine Retention, Slurred Speech, Limb Weakness, Numbness <i>and/or</i> Pain at Injection Site and a Lumbar Puncture, MRI or CT Guided Biopsy after MPA Injection | 1 |
| Category VII | No Symptoms or No Lumbar Puncture, MRI, or CT Guided Biopsy after MPA Injection | 1/2 |

² Including vertebral osteomyelitis, discitis, sacroiliitis, phlegmon, abscess and/or arachnoiditis.

³ *E.g.*, hip, knee, shoulder, elbow and/or ankle.

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The first five categories of the Matrix are based on five of the categories of conditions/illnesses defined by the CDC. Two additional categories were added: (1) one or more symptoms with lumbar puncture, MRI or CT guided biopsy⁴ and (2) no symptoms or no lumbar puncture, MRI or CT guided biopsy (a/k/a “fear cases”). The final two categories are expected to have the largest number of claims.⁵ A claimant may apply only for one of the seven Base Point Categories.

Each of the first six Base Point Categories has a variety of upward adjustments for aggravating circumstances. This provides a method to cover the range from mild cases to extremely serious cases in each such Base Point Category. For example, our consulting physicians advised that a fungal infection of the sacroiliac joint (the joint at the bottom of the spine) is more serious than other areas of the spine and that arachnoiditis and vertebral osteomyelitis are more serious than other types of spinal/paraspinal infections in Categories II and IV. All of the upward adjustments available in these categories⁶ are efforts at providing more compensation for the more serious cases in a particular category.

The Matrix provides that, for claims involving NECC products other than the Three Contaminated MPA Lots, the claimant must establish that the lot of NECC product administered to the claimant was contaminated, *i.e.*, one of the 9 lots of non-MPA found to be contaminated after the CDC tested numerous lots of compounds from NECC.⁷ For all claims involving alleged bacterial contamination, the claimant must establish that the specific bacteria that caused the bacterial infection or bacterial meningitis in the claimant was present in the lot of the NECC product administered to the claimant.⁸ Loss of consortium and family member claims will not receive separate compensation.

The Settlement Administrator(s) Allocates Points to Victims Based on the Matrix.

To receive compensation from the Tort Trust, claimants must submit a completed and signed Compensation Claim Form applying for one of the Seven Base Point Categories (as well as any applicable Adjustments) to the Settlement Administrator, together with all supporting

⁴ Lumbar punctures, MRIs, and CT guided biopsies were used by physicians to determine if a diagnosis of fungal meningitis and/or fungal infection may be made in a patient.

⁵ It is estimated that there may be 500 – 1,000 claims filed under each of these two categories.

⁶ *I.e.*, Lengthy Hospitalization Adjustment, Surgical Debridement and/or Irrigation Surgery Adjustment, Anti-Fungal Complication Adjustment, Length of Anti-Fungal Treatment Adjustment, Stroke Adjustment, Multiple Lumbar Punctures or CT Guided Biopsies Adjustment, Income Adjustment.

⁷ It is estimated that there will be approximately 50 “other product” claims and that the majority will involve bacterial infections.

⁸ These other types of claims, are dealt with slightly differently than those involving the Three Contaminated MPA Lots and fungal meningitis or fungal infections for a number of reasons: 1) the CDC has not linked any NECC product that was compounded in 2012 other than one of the Three Contaminated MPA Lots to any injury or illness; 2) the CDC tested numerous compounds from NECC and found only 9 non-MPA lots to be contaminated; 3) the CDC has not linked any case of bacterial infection or bacterial meningitis to any NECC product that was compounded in 2012, including the Three Contaminated MPA Lots; and 4) as opposed to fungal meningitis and fungal infections, bacterial infections are quite common (as just an example, there are over 500,000 cases of staph infections annually in the U.S).

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documentation required, by 120 days after the Plan Effective Date. Claimants who did not previously file a Personal Injury Tort or Wrongful Death Addendum (“PITWD”) by the bar date set by the Bankruptcy Court– or who were not expressly granted permission to file a late claim by the Bankruptcy Court – will *not*, now, be able to submit a claim for compensation.

The Settlement Administrator will review and make determinations on the claims in the National Settlements, and, possibly some or all of the Clinic Settlements.⁹ Contributions to the Tort Trust from the National Settlements will be allocated according to the Matrix.¹⁰

As soon as possible after the Claims Deadline, the Settlement Administrator will initially review all Compensation Claim Forms. If a claimant did not file a timely PITWD Addendum, the Settlement Administrator will deny the Claimant’s claim and notify the Claimant of the final denial.¹¹

The Settlement Administrator will then calculate the total points claimed for all remaining claims and a tentative dollar value of each point, based on the universe of claims and a pre-set formula disclosed in the Plan (“tentative point value”). The Settlement Administrator will then review all remaining claims in the order that they were received.

The Tort Trustee sends each victim a check for his or her initial claim value.

If a claim is allowed in full, the Settlement Administrator will notify the Tort Trustee of the Allowed Claim; the Tort Trustee will send a check to the claimant for the amount of the claimant’s approved points multiplied by the tentative point value (the “initial claim value”).

If a claim contains a deficiency, or otherwise warrants a provisional denial, the Settlement Administrator will send the claimant a Notice of Provisional Denial. Provisional Denials may be either denials in full (i.e. the Claimant does not qualify for the Base Point category applied for) or denials in part (i.e. the Claimant does not qualify for one or more of the upward Adjustments applied for). Claimants then have 90 days to attempt to cure the deficiency, request re-review for error, or request reconsideration under a different Base Point Category.¹² All such submissions shall then be reviewed by the Settlement Administrator who will then issue final determinations on those Claims.

⁹ It is currently undecided whether there will be separate Settlement Administrators for the Clinic Settlements.

¹⁰ Clinic Settlements may be allocated by using the Matrix (only), the Matrix and additional factors, or other factors entirely. Details of allocating clinic-specific pots are still being addressed by counsel.

¹¹ The Claimant will have the right to appeal a Settlement Administrator’s denial to the Magistrate. If there is such an appeal, the Settlement Administrator will forward a copy of the Claimant’s Claim File to the Magistrate, and upon resolution of the appeal, further process the claim as described in more detail below.

¹² If a claimant does not either attempt to cure a deficiency, request a re- review for error or request reconsideration under a different Base Point Category, within 90 days of the Notice of Provisional Denial, the claimant will be deemed to have waived the right to appeal the Settlement Administrator’s Provisional Denial of the claim to the Magistrate. If the Provisional Denial was a partial denial which included an award of approved points and an initial claim value, the Settlement Administrator will notify the Tort Trustee of the amount of the claimants approved points and the initially calculated claim value. The Tort Trustee will then write the appropriate check.

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Appeals to the Magistrate.

All victims receiving a final determination from the Settlement Administrator¹³ may appeal the award to the Magistrate within 30 days.¹⁴ The appeal must include a written statement setting forth the basis for the appeal. For example, an appellant must explain that the Settlement Administrator erred in failing to consider (i) proof establishing qualification for a base point category (*e.g.*, a medical record confirming a fungal meningitis diagnosis) or (ii) proof to support an upward adjustment (*e.g.*, an entries in medical records reflecting the number of nights of hospitalization).

In the event of an appeal, the Magistrate will:

- (i) perform a de novo evaluation of each appealed claim in accordance with the Matrix,
- (ii) make a final determination of the number of approved points allowed for each appealed claim,¹⁵ and
- (iii) inform both the victim and the Settlement Administrator, in writing, the amount of the final determination.

The Magistrate will *not* have discretion to award points or dollars in a manner that is inconsistent with the Matrix. The Matrix governs the appeal.

The Magistrate's determination will be final and binding. There will not be, for example, an ability to appeal the Magistrate's determination to the MDL Court or Bankruptcy Court.

The Tort Trustee sends victims another check for the difference between the initial payment and the final compensation amount.

Within 120 days after all appeals are resolved by the Magistrate and after any appeals of the Confirmation Order are finally resolved, the Settlement Administrator shall compute the final dollar value of each Approved Point by employing a pre-set formula.

The Settlement Administrator shall then determine the final compensation amount for each Approved Claim ("Final Compensation Amount") by multiplying the Approved Points times the Final Point Value on each Approved Claim. Promptly thereafter, the Settlement Administrator shall notify the Tort Trustee to make the following disbursements:

¹³ Except victims who have waived the right of appeal by failing to attempt to cure a Provisional Denial with the Settlement Administrator within 90 days.

¹⁴ The only other possible category of appeals that may come before the Magistrate is an appeal from the Settlement Administrator's final determination that a Compensation Claim Form which was filed after the Claims deadline was not the result of excusable neglect.

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1. If the Final Point Value exceeds the Tentative Point Value, then each Claimant who received an Initial Payment shall be paid an additional amount equivalent to the difference between the Claimant's Final Compensation Amount and the Initial Payment.
2. All other Claimants whose claim has been approved in whole or in part shall be paid an amount equivalent to the Claimant's Final Compensation Amount.

Within ninety (90) days after all Allowed Claims have been finally paid by the Tort Trustee, the Settlement Administrator shall wind up the affairs of the Claims Resolution Facility and the Settlement Administrator and the Tort Trustee shall file a joint final report with the Bankruptcy Court. The final report shall specify the total number of claims filed in each of the seven Base Point Categories, the Tentative Point Value of each point, the Final Point Value of each point, the total number of Qualified Claims in each category, the total number of points awarded in each category, and the total amounts paid to each Claimant in each category.

Conclusion.

The PSC hopes Your Honor is willing to hear appeals from victims awarded funds through the bankruptcy settlement Based on the processes described above. We believe Your Honor's skill, experience, temperament, and understanding of the case will bring a unique sense of fairness and public confidence to the process. Thank you for your consideration.

Sincerely,

/s/ Kristen A. Johnson

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Cc: The Honorable Rya W. Zobel